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METHOD DEVELOPMENT AND VALIDATION OF FAMOTIDINE BY USING RP-HPLC METHOD IN PHARMCEUTICAL FORMULATION

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ABSTRACT

This work describes a strategy for the systemic development of HPLC method for Method development and validation of Famotidine by using RP-HPLC method in pharmaceutical formulation. A simple, economical, precise, and accurate method was developed and validated by Reverse Phase High Performance Liquid Chromatography (RP-HPLC). The main objective for that is to improve the conditions and parameters, which should be followed in the development and validation. The developed Reverse phase HPLC technique was done utilizing filtered and degassed pH-6.0 Acetate buffer as a Mobile phase-A and pH-6.0 Acetate buffer and organic mixture in the ratio of 30:70 as a Mobile phase-B. By using waters X- Bridge C18 (150*4.6mm), 3.5µm column chromatographic separation was achieved. The flow rate and run time was 0.7mL/min and 10minutes. The detection wavelength was 220nm.The average percentage recovery for Famotidine related compound-C was found to be 94.3%, 95.9%, 96.0% represents the accuracy of the method and for Famotidine related compound was found to be 95.8, 95.4 and 96.4. The %RSD for Famotidine related compound-C was found to be 5.576 and for Famotidine related compound was found to be 1.588 represents the precision of the method. The correlation coefficient square for Famotidine, Famotidine related compound-C and Famotidine related compound-D was found to be 0.999999, 0.9992 and 0.9991 respectively. Respective parameters met the acceptance criteria.

INTRODUCTION

Famotidine is a competitive histamine-2 (H2) receptor antagonist that works to inhibit gastric acid secretion. It is commonly used in gastrointestinal conditions related to acid secretion, such as gastric ulcers and gastroesophageal reflux disease (GERD), in adults and children. Compared to other H2 receptor antagonists, famotidine displays high selectivity towards this receptor; in a study consisting of healthy volunteers and patients with acid hypersecretory disease, famotidine was about 20 to 50 times more potent at inhibiting gastric acid secretion than cimetidine and eight times more potent than ranitidine on a weight basis. Famotidine is used in various over-the-counter and off-label uses. While oral method development and validation of famotidine by using rp-hplc formulations of famotidine are more commonly used, the intravenous solution of the drug is available for use in hospital settings. Famotidine is a histamine H2 receptor antagonist used to treat duodenal ulcers, benign gastric ulcers, GERD, and Zollinger-Ellison syndrome. The intravenous formulation of famotidine is available for

some hospitalized patients with pathological hypersecretory conditions or intractable ulcers or as an alternative to the oral dosage form for short-term use in patients who are unable to take oral medication.

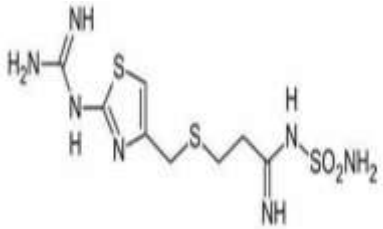


Fig.1: Famotidine

MATERIALS AND METHODS:

Instrument: The liquid chromatographic system consisted of Shimadzu HPLC model (VP series) containing LC-10AT (VP series) pump, variable wave length programmable UV/visible detector SPD10AVP and rheadyne injector (7725i) with 20µl fixed loop. Chromatographic analysis was performed using Interrail ODS Ultra sphere 5 µm or equivalent ODS C-18 column with 4.6 mm x 15cm internal diameter and 5µm particle size. Shimadzu electronic balance (AX-200) was used for weighing purpose. Methanol of HPLC Grade was purchased from E-Merck, Mumbai, India. Lc grader water was obtained by double distillation and purification through Milli-Q water purification system.

The Mobile Phase: A mixture of Methanol: Water in the ratio of 65: 35 v/v was prepared and used as mobile phase.

Preparation of mobile Phase: Accurately measured 80 ml of Acetonitrile and 20 ml of methanol were mixed by using sonication for 5 min.

Diluent preparation: The mobile phase was used as the diluent**.**

Blank Preparation: Place unused swab in 10 ml of solvent. Sonicate for 5 minutes. Squeeze swab out well. Filter through a 0.45 µm filter.

Preparation of Standard solution (Stock Solution): A stock solution of famotidine was prepared by Accurately weighing 50 mg of Famotidine transferring to a 100 ml volumetric flask, dissolving in 60 ml of solvent and sonicate for 15 minutes, cool and make up to volume with solvent. Appropriate aliquot of this solution was further diluted with solvent to 100 ml with solvent. Dilute 5 ml of this solution to 50 ml with solvent. Filter through a 0.45 µm filter. From (0.05 mg/ml) stock solution below, a series of standard solutions were prepared. Seven solutions containing 0.05, 0.025, 0.0125, 0.0062, 0.003125, 0.0015625 and 0.0007812 mg/swab of famotidine, relative to the working concentrations, were prepared and injected according to the method of analysis. A linear regression curve was constructed.

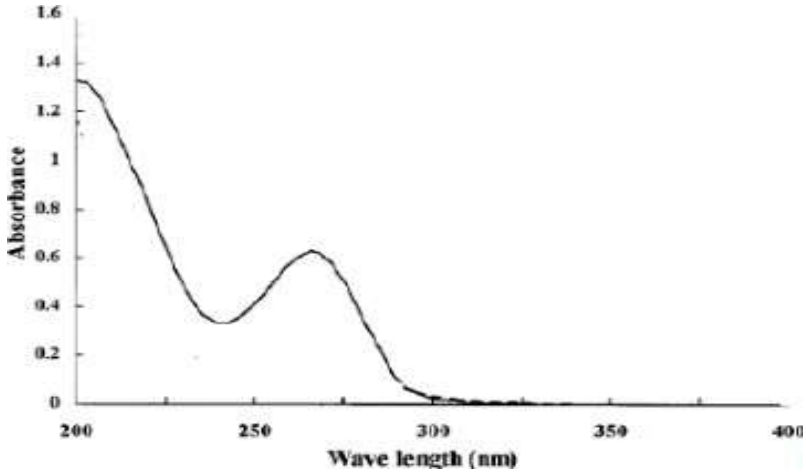
Preparation of sample solution: Accurately weigh 10 tablets crush in motor and pestle and transfer equivalent to 150 mg of famotidine sample into a 100 ml clean dry volumetric flask add about 50 ml of diluent and sonicate it up to 30 min to dissolve it completely and make up to the mark with the same solvent. Then it is filtered through 0.45-micron injection filter. Further pipette 2.5 ml of the above stock solution into a 25 ml volumetric flask and dilute up to the mark with diluent. Further pipette 3 ml of the above stock solution into a 10 ml volumetric flask and dilute up to the mark with diluent.

Procedure: Inject 10µl of the standard solution, sample into the chromatographic system and measure the areas for famotidine peaks and calculate the % assay by using the formulae.

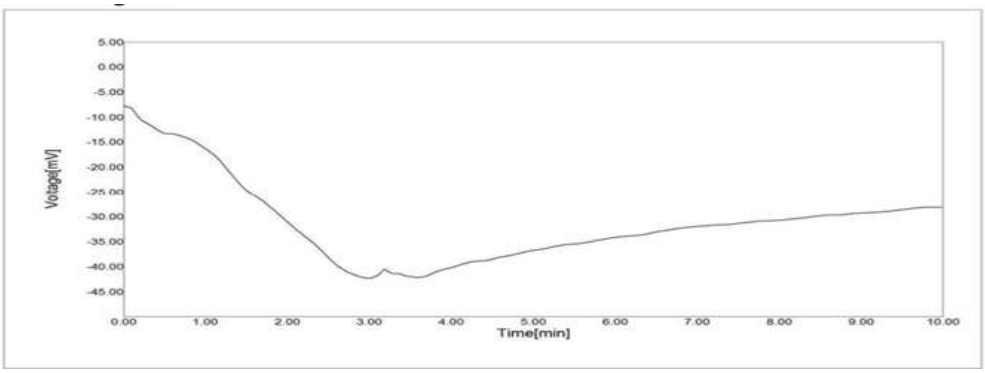
Linearity: Accurately weigh and transfer 150 mg of Famotidine working standard into a 100ml clean dry volumetric flask add about 50 ml of diluent and sonicate to dissolve it completely and make up to the mark with the same solvent. Further pipette 2.5ml of the above stock solution into a 25ml volumetric flask and dilute up tomark with diluent.

Precision: Accurately weigh 200 mg of Famotidine reference standard into a 50 ml volumetric flask. Add 20 ml of solvent and sonicate for 15 minutes, cool and make up to volume with solvent. (Solution 1 to be used for sample preparation). Dilute 10 µl to 10 ml with solvent. Filter through a 0.45 µm filter. Place 10 µl of solution 1 onto a specific surface area of stainless-steel plate. Swab the surface area; take the swab stick and place into a 10 ml volumetric flask. Add 10ml of solvent and sonicate for 10 minutes.

Fig .02 - wavelength scanning in UV-Visible spectrophotometer



Chromatogram for Blank:



LINEARITY:

Level	Concentration(µg/ml)	peak area
Level – 1	10 µg/ml	163
Level – 2	20µg/ml	1545
Level – 3	30µg/ml	2061
Level – 4	40 µg/ml	3752
Level – 5	50µg/ml	4302
Level - 6	60µg/ml	5319

CALIBRATION CURVE:

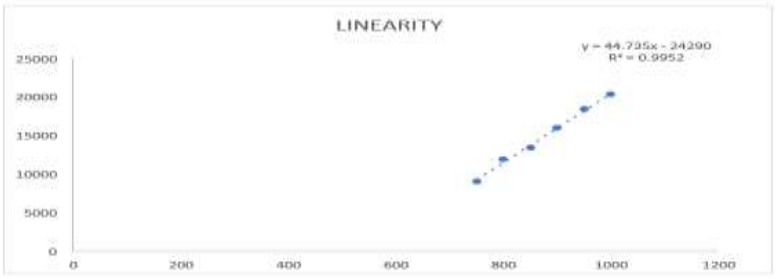


FIG.03 – Calibration curve

PRECISION:

S.NO	Injection	Area value
1	Injection 1	13450.15
2	Injection 2	11946.06
3	Injection 3	11152.52
4	Injection 4	13581.15
5	Injection 5	9087.03
6	Injection 6	14674.79

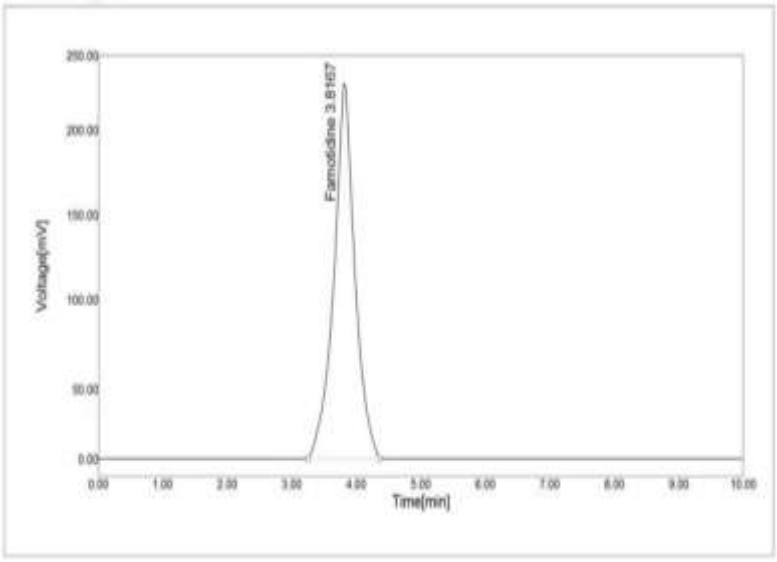


Fig.04 – Formulation result

Filter through a 0.45 µm filter. The % recovery should be greater than or equal to 65%

RESULTS AND DISCUSSION:

Estimation of Wave length: The wavelength of famotidine was estimated as 220nm

Formulation: The sample solution prepared at a concentration of 100µg/ml was analysed in the developed method conditions. The method can successfully separate and identify the famotidine. Hence the method was found to be suitable for routine analysis of famotidine and formulations. Sample chromatogram was given.

CONCLUSION:

A simple, Accurate, precise method was developed for the s estimation of the famotidine in Tablet dosage form. Retention time of famotidine was found to be 3.74min and 3.97min. %RSD of the famotidine were and found to be 0.1 and 0.5 respectively. %Recover was Obtained as 98.19% and 92.28% for famotidine. LOD, LOQ values were obtained from regression equations of famotidine were 0.30ppm, 0.92ppm and 0.21ppm, 0.63ppm respectively. Regression equation of Famotidine is y =44.843x+2437, Retention times are decreased and that run time was decreased so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

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